

**AMENDMENTS TO THE DRAWINGS:**

The attached drawing sheets include changes to Figure 1. The attached drawing sheets include an annotated and replacement sheet showing changes to Figure 1. Please replace the original drawing sheet containing Figure 1 with the accompanying replacement sheet containing the same figure.

In the replacement sheet, Figure 1 has been amended to change the location of the element number 304, as shown. Moreover, the figure component identified by element 310 has been labeled "pump", as shown.

Attachments:            One (1) Replacement Sheet

                          One (1) Annotated Sheet Showing Changes

**REMARKS**

This communication is a full and timely response to the non-final Office Action dated October 26, 2005 (Paper No./Mail Date 10182005). By this communication, the specification and Figure 1 of the drawings have been amended.

In the specification, paragraph [0024] has been amended to change "...the target flow rate Q will be determined by a function 410 whose value lies..." to "the target flow rate Q will be determined by any of functions 410a, 410b, 410c, or 410d whose values lie..." Support for the changes to the specification can be found variously throughout the specification and drawings, for example, in original paragraph [0024] and Figure 4 of the drawings. No new matter has been added.

Figure 1 has been amended to change the location of the left ventricle identified by element number 304, and to label the figure component identified by element 310 a "pump". Support for the changes to Figure 1 can be found variously throughout the specification, for example, in paragraph [0012]. No new matter has been added.

Claims 1-23 are pending.

**Allowable Subject Matter**

Applicant acknowledges the indication that claims 3-6, 8, 9, 12-15, 17, 18, and 21-23 contain allowable subject matter. However, Applicant believes that rejected claims 1, 2, 7, 10, 11, 16, 19, and 20 are allowable in their current form for the reasons set forth below.

**Objection to the Drawings**

The drawings were objected to for allegedly failing to properly identify the anatomical location of the left ventricle designated by element 304 and allegedly not properly labeling the figure component designated by element 310 as a "pump". Applicant respectfully traverses these objections. However, in an effort to expedite prosecution Applicant has attached both an annotated and a replacement drawing sheet that remedy the alleged deficiencies. Accordingly, Applicant respectfully requests that the objection of Figure 1 be withdrawn.

**Objection to the Specification**

The specification was objected to for including alleged informalities. Applicant disagrees. However, in an effort to expedite prosecution and as discussed above, the specification has been amended in a manner that addresses and remedies this alleged deficiency.

**Rejections Under 35 U.S.C. 112**

Claims 3, 5, 6, 12, 14, and 15 were rejected under 35 U.S.C. 112, first paragraph for allegedly failing to comply with the enablement requirement. In particular, the Office Action alleges that the claim element f(N) as recited in claims 3 and 12 is not defined in any corresponding base claims or in the specification. Applicant respectfully traverses this rejection.

At paragraph [0023], the specification discloses the ratio M is based on the determined heart rate and a function of the mean value of the pump speed N over a time period. The specification further states that the calculation of M is the same as the calculation used to calculate M<sub>max</sub> and M<sub>min</sub>.

At paragraph [0019], the specification discloses that M<sub>max</sub> is calculated based on HR<sub>max</sub> and f(N<sub>min</sub>), where the ratio can be defined as M<sub>max</sub> = HR<sub>max</sub>/(N<sub>min</sub>)<sup>n</sup>. Similarly, M<sub>min</sub> is calculated based on HR<sub>min</sub> and f(N<sub>max</sub>), where the ratio can be defined as M<sub>min</sub> = HR<sub>min</sub>/(N<sub>max</sub>)<sup>n</sup>. Therefore, based on at least the disclosure in paragraphs [0019] and [0023] of the specification, Applicant respectfully submits that it should be readily apparent to one of ordinary skill in the art that if the calculation of M is the same as the calculation of M<sub>max</sub> and M<sub>min</sub>, M can be defined as M=HR/f(N) as recited in claims 3 and 12.

In response to this contention, it is incumbent upon the Patent Office that whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning that is inconsistent with the contested statement. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (1971).

Please note that section 112 requires only an objective enablement; the invention needs to be sufficiently disclosed through illustrative examples or terminology to teach those of ordinary skill in the art how to make and how to use the invention as broadly as it is claimed. *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). See also

M.P.E.P §§2164.01, 2164.04. "The applicant does not have to utilize any particular form of disclosure to describe the subject matter claimed." *In re Alton*, 76 F.3d 1168, 1172, 37 USPQ2d 1578, 1581 (Fed. Cir. 1996). For at least the foregoing reasons, Applicant respectfully requests that the rejection of claims 3 and 12 under 35 U.S.C. 112, first paragraph be withdrawn.

Claims 5, 6, 14, and 15 depend from claim 3 or 12, where applicable. By virtue of this dependency, Applicant respectfully submits that these claims are also enabled by the specification. Accordingly, Applicant respectfully requests that the rejection of claims 5, 6, 14, and 15 under 112, first paragraph be withdrawn.

#### **Rejections Under 35 U.S.C. 102**

Claims 1, 2, 7, 10, 11, 16, 19, and 20 were rejected under 35 U.S.C. 102(b) as anticipated by *Medvedev et al.*, US 2004/0152944. Applicant respectfully traverses this rejection.

Claim 1 is directed to a method for controlling a blood pump connected to a patient. This method includes, among other things, the step of calculating a ratio of said heart rate value and said speed value.

Claim 10 is directed to a blood pump system for assisting a patient's heart. This system includes, among other things, a controller that regulates the speed of the pump based on a ratio of the patient's heart rate and the speed of the pump.

Claim 19 is directed to a machine readable medium comprising a computer program that executes the process of regulating the speed of a blood pump connected to a patient, based on a ratio of the patient's heart rate and the speed of the pump.

*Medvedev* discloses a chronic performance control system for rotodynamic blood pumps that uses two pump flow control methods. The first method uses only the patient heart rate to define the desired target flow. The second method uses a heart rate to systemic pressure ratio (HR:P) to define the target flow. *Medvedev*, however, fails to disclose, teach, or suggest at least calculating a ratio of said heart rate value and said speed value, as recited in claim 1, a ratio of the patient's heart rate and the speed of the pump, as recited in claim 10, or regulating the speed of a blood pump connected to a patient based on a ratio of the patient's heart rate and the speed of the pump.

The Office Action alleges that because the flow rate is dependent upon the speed of the motor, the speed is also proportional to the heart rate. The Office Action, however, fails to appreciate the fact that a rotodynamic LVAD flow depends on several factors including systemic pressure, percent of systole, and LV contractility, among others. Based on at least these factors it should be readily apparent to one of ordinary skill in the art that an increase in heart rate due to patient exercise often leads to the controller reducing the pump speed because under the new physiologic conditions the pump flow rate may reach a level above the target flow rate.

The Office Action further alleges that because *Medvedev* teaches the microprocessor communicating a new power output to regulate power to the motor, it follows that *Medvedev* teaches adjusting the speed of the pump based on a desired speed to heart rate ratio. The teachings of *Medvedev*, however, are juxtaposed to this assertion. As discussed above, *Medvedev* teaches that pump flow is regulated based on a heart rate to systemic pressure ratio (HR:P). The systemic pressure P depends on many factors including pump speed, but it is not directly related or proportional to the pump speed. In fact, at paragraph [0082] *Medvedev* teaches away from using the pump speed to regulate the pump flow. *Medvedev* merely uses the pump speed to calculate the actual pump flow that depends on many factors including the physiologic condition of the patient.

To properly anticipate a claim, the document must disclose, explicitly or implicitly, each and every feature recited in the claim. See Verdegall Bros. v. Union Oil Co. of Calif., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). *Medvedev* fails to disclose, teach, or suggest every element recited in independent claims 1, 10, and 19. Therefore these claims are not anticipated by this reference. Accordingly, Applicant respectfully requests that the rejection of claims 1, 10, and 19 under 35 U.S.C. §102 be withdrawn, and these claims be allowed.

Claim 2 depends from claim 1, claim 11 depends from claim 10, and claim 20 depends from claim 19. Each of claims 2, 11, and 20 additionally recite that the speed of the pump is regulated to achieve a target flow rate that is a monotonic function of said ratio within a defined range of flow rates.

*Medvedev* teaches that the relationship between the motor power and pump flow rate can be expressed as  $Q = \phi(S_{elec} / \omega^2)$ , where  $\phi$  is a monotonic function within the pump

operating range. The Office Action alleges that because Q has a linear correlation with  $\varphi$ , the speed of the pump is regulated to achieve a target flow rate that is a monotonic function of said ratio within a defined range of flow rates. The aforementioned equation for Q, however, is used to calculate an actual pump flow not the target or desired flow, which can be quite different from the actual flow. This equation is specific to a specific pump and does not represent a relationship between a patient and his/her physiologic demand that is satisfied by the target flow. The equation of *Medvedev* noted above, uses a pump power to squared pump speed ratio. This equation must be monotonic so that the controller may calculate the pump flow, and is related to only a pump of a specific type and size not a desired physiologic target pump flow.

*Medvedev* fails to disclose, teach, or suggest every element recited in claims 2, 11, and 20, therefore these claims are not anticipated by this reference. Accordingly, Applicant respectfully requests that the rejection of claims 2, 11, and 20 under 35 U.S.C. §102 be withdrawn, and these claims be allowed.

Claim 7 depends from claim 1 and claim 16 depends from claim 10. Each of claims 7 and 16 additionally recite changing the pump speed when flow pulsatility falls below a first threshold.

As discussed above, *Medvedev* discloses that the controller regulates the power delivered to the pump to achieve the target flow. The pump speed is neither regulated nor set by the controller. Furthermore, *Medvedev* teaches that the pump speed can vary during the cardiac cycle and serves only as one of the variables for actual flow calculations and for pump operational safety checks.

*Medvedev* fails to disclose, teach, or suggest every element recited in independent claims 7 and 16, therefore these claims are not anticipated by this reference. Accordingly, Applicant respectfully requests that the rejection of claims 7 and 16 under 35 U.S.C. §102 be withdrawn, and these claims be allowed.

**Conclusion**

Based on at least the foregoing amendments and remarks, Applicant submits that claims 1-23 are allowable, and this application is in condition for allowance. Accordingly, Applicant requests a favorable examination and consideration of the instant application. In the event the instant application can be placed in even better form, Applicant requests that the undersigned attorney be contacted at the number listed below.

Respectfully submitted,

BUCHANAN INGERSOLL PC

Date: January 24, 2006

By:   
James A. LaBarre

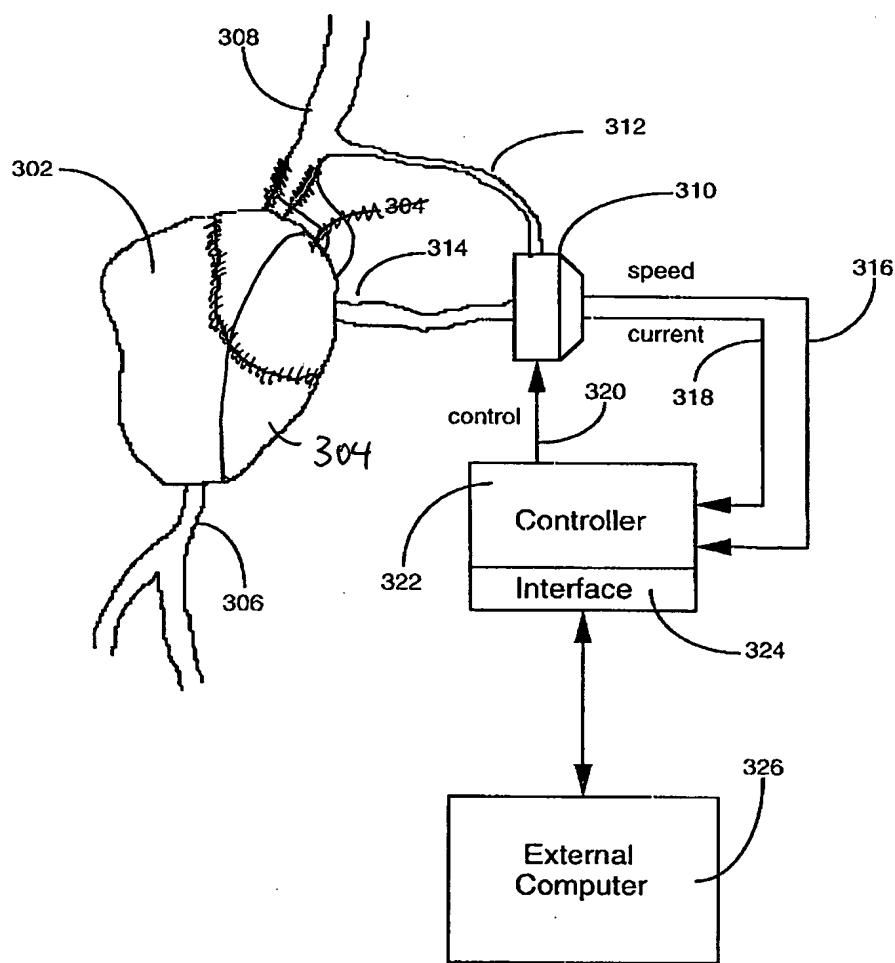
Registration No. 28,632

Shawn B. Cage  
Registration No. 51,522

P.O. Box 1404  
Alexandria, Virginia 22313-1404  
(703) 836-6620



## Annotated Sheet



*Fig. 1*